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EXAMINER

SINES, BRIAN J

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/760,384

Applicant(s)

DUONG ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1 – 9, drawn to a biochip cartridge utilizing an array of electrodes, classified in class 422, subclass 82.01.
- II. Claims 10 – 23, drawn to a device for multiple biochip analysis comprising at least two stations configured to receive a biochip cartridge, classified in class 422, subclass 50.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as subcombination and combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the device is configured to receive a biochip cartridge, which does not require the same structure as the biochip cartridge of the subcombination. The subcombination has separate utility, such as the biochip cartridge being used with another device not requiring at least two stations.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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During a telephone conversation with Renee M. Kossiak on 6/20/2003 a provisional election was made without traverse to prosecute the invention of group II, claims 10 – 23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1 – 9 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10 – 16, 18, 19, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Kercso et al. (U.S. Pat. No. 6,132,685 A). Regarding claim 10, Kercso et al. teach a device for multiple biochip analysis comprising at least two stations, such as a dilution station (24) and a test station (26), wherein the device is configured to receive a biochip cartridge (microfluidic device, 40) (see col. 7, lines 7 – 17; col. 10, lines 33 –

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44). Regarding claims 11 and 12, Kercso et al. teach selective thermal control (see col. 1, lines 47 – 51; col. 16, lines 39 – 45). Regarding claim 13, Kercso et al. teach signaling systems (see col. 16, lines 59 – 66). Regarding claims 14 and 16, Kercso et al. teach a memory chip reader and writer (see col. 14, lines 42 – 56). Regarding claim 15, Kercso et al. teach that the device comprises a bar code reader station (22), (see col. 7, lines 7 – 17). Regarding claim 18, Kercso et al. teach the incorporation of multiple biochip cartridges or microfluidic devices (see col. 17, lines 46 – 58). Regarding claim 19, Kercso et al. teach the incorporation of a liquid handling system (see col. 2, lines 29 – 44; col. 8, lines 39 – 65). Regarding claim 21, Kercso et al. teach the incorporation of a device board, such as a memory board (see col. 14, lines 42 – 56). Regarding claim 22, Kercso et al. teach the use of a processor (see col. 14, lines 42 – 56).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al. in view of Beecham (U.S. Pat. No. 5,876,926 A). Kercso et al. is silent to the specific teaching of the system further comprising an encryption system. Kercso et al. do teach that that system may be used in diagnostic medicine (see col. 2, lines 1 – 12). Beecham teaches a method and apparatus for collecting medical data from a test subject while preserving the anonymity of the test subject (see entire reference). It would have been obvious to one of ordinary skill in the art to incorporate an anonymous encryption system, as taught by Beecham, with the medical diagnostic system, as taught by Kercso et al., in order to provide a means for maintaining patient confidentiality for medical test results.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al. in view of Przygoda, Jr. et al. (U.S. Pat. No. 5,438,607 A). Kercso et al. do not specifically teach that the system may further comprise a wireless communication component. Kercso et al. do teach that that system may be used in diagnostic medicine (see col. 2, lines 1 – 12). Przygoda, Jr. et al. do teach a medical monitoring system, which incorporates the use of a wireless system (see col. 1, lines 1 – 68; col. 2, lines 1 – 30). It would have been obvious to one of ordinary skill in the art to incorporate the wireless medical monitoring system, as taught by Przygoda, Jr. et al., with the medical diagnostic system, as taught by Kercso et al., to facilitate effective monitoring of any medical emergencies.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kercso et al. in view of Phipps (U.S. Pat. No. 6,579,231 B1). Kercso et al. do not teach the further incorporation of a global positioning system with the medical diagnostic system. Kercso et al. do teach that that system may be used in diagnostic medicine (see col. 2, lines 1 – 12). Phipps does teach a medical monitoring system, which incorporates a global positioning system for keeping track of a monitoring device in case of medical emergencies (see col. 2, lines 20 – 65). It would have been obvious to one of ordinary skill in the art to incorporate a global positioning system, as taught by Phipps, with the medical monitoring system, as taught by Kercso et al., in order to locate the medical monitoring system in an emergency.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tayi teaches an automated analytical system, which incorporates the use of reagent packs, test sample containers and reaction vessels, for performing multiple assays. Besemer et al. teach a microfluidics system, which uses assay cartridges. Winkler et al. teach a device for holding assay cartridges used for mixing fluids. Furcht et al. teach a genetic testing system using a genetic test card or cartridge. Chow et al. teach a microfluidic analysis device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (703)


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305-0401. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

BJS  
June 24, 2003

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700